

## REMARKS

Reconsideration is respectfully requested in view of the remarks which follow and the attached Rule 132 Declaration by Dr. Irina Rappaport, one of the co-inventors herein.

The claims presently pending in the application are 1-25, inclusive.

A new first paragraph has been added to the specification which makes specific reference to the prior-filed application in compliance with 37 C.F.R. 1.78(a) and the priority of the Italian application. In addition, the reference includes the relationship in order to claim the benefits under 35 USC 120 and 35 USC 121.

Claims 1-25 stand provisionally rejected for nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5 and 7-23 of co-pending application serial number 10/104,410. Applicants include herewith timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 which serves to overcome the provisional rejection based upon nonstatutory double patenting since the conflicting application is commonly owned with this application. Accordingly, withdrawal of the nonstatutory double patenting rejection is respectfully solicited.

Claims 1-10 and 16-25 stand rejected under 35 USC §103 as being unpatentable over EP 302 536 in view of US 5,631,011 and the article by Fialkova et al. This rejection is respectfully traversed.

While the primary reference employed by the Examiner, EP '536, discloses a hydrocolloidal patch, it fails to foresee or disclose the inclusion of a wound healing promoter.

The secondary reference employed by the Examiner, namely, US '011, it teaches a fibrin or fibrinogen glue for treating wounds. In other words, it teaches a glue which is supplemented with a biodegradable and biocompatible polymer. The role of the polymer is to provide adequate viscosity for the glue to improve its rheology. Thus, the teaching of using hyaluronic acid as biodegradable and biocompatible polymer in a glue, does not begin to equate to its claimed use herein as a pharmaceutically active substance, especially in view of the fact that it is said to display only limited *bioavailability*. (Col. 4, lines 20-22 of the '611 reference.) Purely and

simply, US '011 teaches that hyaluronic acid is a *safe thickening agent for fibrin glues*. The '011 reference does not disclose or teach the use of hyaluronic acid in the context of the presently claimed invention.

The other secondary reference relied upon by the Examiner, the article by Fialkova et al., teaches the use of an injectable solution of chondroitin sulfate to stimulate the regeneration of skin after injury. The therapeutic form is said to be a 10% aqueous solution of chondroitin sulfate.

Applicants, unexpectedly found, as stated by Dr. Rappaport in her Declaration, that the use of smaller quantities of chondroitin sulfate produced results, as set forth in the examples, which were synergistic in nature and completely unexpected in view of the vastly larger quantities which were reported in the Fialkova et al. article.

One of ordinary skill in the art would never expect from the teaching of Fialkova et al., that using chondroitin sulfate having a concentration of only 0.01% to 5%, by weight, in a patch would produce such significant improvements in the rate and quality of the healing.

Let us assume, for the sake of discussion, a scenario wherein the applicants herein had been inspired by the teaching of Fialkova et al. What course of action would they have taken? They would first have started with testing of Group A (placebo) and Group C (medium concentration). As a result of such testing, they would have found that the invention does not work at all. Looking further at the Fialkova reference, the applicants herein would then have deemed the quantities employed as being too small, rather than too large. Thus, one of ordinary skill in the art would, based on Fialkova et al., have started a new round of testing using larger quantities. Thus, the teaching of Fialkova et al., would lead totally away from, and in addition opposite, *from the invention as claimed herein*.

As can be seen from the results in the application - - in particular the overall results - - there can be no doubts, realistically, about the technical progress which was achieved, seen that B and D cicatrize the fastest, *but* B displays, at the same time, a more mature, deep dermis with denser collagen formation. Thus B is, without any doubt, the most successful experiment, if *all* of the observed factors are taken into account.

It is respectfully submitted that the §103(a) rejection of claims 1-10 and 16-25 have been overcome and, accordingly, should be withdrawn.

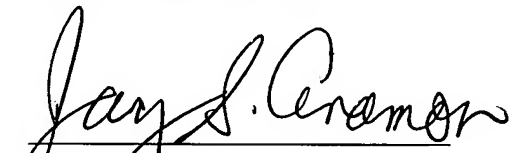
The rejection of claims 11-15 under 35 USC 103(a) over EP '536 in view of US '011 and Fialkova and further in view of US 6,190,689. This rejection is respectfully traversed.

Since claims 11-15 depend directly or indirectly from independent claim 1, and that claim is deemed to have overcome the §103(a) rejection referred to previously, then claims 11-15 also serve to distinguish over the combination of art applied by the Examiner. Accordingly, withdrawal of this §103(a) rejection is also respectfully solicited.

The issuance of a Notice of Allowance is respectfully requested.

Please charge any fees which may be due which have not been submitted herewith to our Deposit Account No. 01-0035.

Respectfully submitted,

  
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